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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,079	10/13/2000	Robert E. Herman	F-5076-DIV	8404

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT

PAPER NUMBER

1627

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/688,079

Applicant(s)
Herman et al

Examiner
Padmeshri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 10, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-62 and 70-76 is/are pending in the application.
- 4a) Of the above, claim(s) 44-61 and 71-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-43, 62, and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Oct 13, 2000 is: a) ☐ approved b) ☒ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election of group I, claims 38-43, 62-70 are in Paper No. 7, filed on 5/10/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 44-61, and 71-76 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
3. Claims 1-37 and 63-69 have been canceled by the amendment filed on 10/13/00.
4. Claims 38-61, 70-76 are currently pending in this application.
5. Claims 38-43, 62 and 70 are currently being examined in this application.
6. The preliminary amendment A, filed on 10/13/00 has been fully considered, and entered in part.

The amendment to the drawings and to the specification pages 15, 16 and 18, has been considered and not have been entered, since it introduces new matter.

7. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10/13/00 have been disapproved because they introduce new matter into the drawings. 37 CAR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of changes to the drawings.

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8. This application has been filed with informal drawings. Applicant is invited to notice that boxes 3, 5, and 10 were checked by the draftsman in PTO 948. If applicants plan to amend the drawings or figure numbers, applicants are encouraged to amend the specification so that the description of renumbered figures in the specification corresponds to the renumbered figures.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 is vague and indefinite by reciting 'a first filtration media coupled to the tubing' and 'second filtration media coupled to the tubing'. Since the claims are drawn to a kit, it is not clear how the first filter and second filter are attached to the tubing. Are they attached to the tubing after the blood component are exposed to photo activating agent or before.

Claim 70 is also indefinite by reciting '..first cellular species...second cellular species..' it is not clear what does applicants mean by first cellular species and second cellular species. Does applicants mean by more than one type of viral or infectious agents or does applicants mean blood components (i.e., different factors). Applicants are requested to clarify.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 38-43, 62, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,319,662 B1 (Foley et al).

The instant claims briefly recite a kit comprising a tubing , a transfer container, photo active material, and an overlap enveloping at least a portion of the kit.

Foley et al teach a method and apparatus for treating a body fluid to at least substantially inactivate viral contaminants that may be present therein. The reference in figure 1, discloses a container 10 (refers to the transfer container of the instant claims) including the blood component, and the blood component is added to the viral inactivating agent 13 (refers to photo activating material of the instant claims). The reference teaches that the viral inactivating agent can be methylene blue (i.e., see column 4) (refers to instant claim 39) or psoralen (i.e., see column 2, line 67) (refers to instant claim 42). The reference teaches that the container 10 will

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include a fluid line 12 (refers to the tubing of the instant claims) that will be coupled to a column (i.e., see column 4, lines 42-43). The reference teaches that the after ~~the~~ container containing the blood product and viral inactivating agent is activated by light of an appropriate wavelength, the resultant product flows through fluid line 12 into the affinity column 14. The affinity column 14 will remove excess viral inactivating agents as well as photo products (i.e., see column 4, lines 58-63). The reference teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines (refers to the instant claim 41). The reference in example 3 teaches the method of treating blood component with methylene blue and photo activating the blood component and filtering the product to remove the remaining photo activating agents.

The claimed invention differs from the prior art teachings by reciting a kit; and a kit comprising a first filtration media and second filtration media; and fist and second blood cellular species.

However, based on the reference disclosure of apparatus, it would be obvious to one skilled in the art at the time of the invention to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime. The reference does not recite two different filtration media to eliminate two different species of blood components. However, the reference teaches that the irradiated blood components are passed through different types of filters to remove the excess viral inactivating agent and photo products. Thus it would have been

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obvious to one skilled in the art at the time the invention was made to use different filters to remove different components, such that selected blood components are obtained.

13. Claims 38-43, 62, are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,300,019 (Bischof et al) and US Patent 6,319,662 B1 (Foley et al).

Foley et al has been discussed supra.

Bischof et al teach a system and methods for eradicating contaminants using photo active materials in fluids like blood. The reference teaches that the device includes an outer wall that defines the interior area. The outer wall is transparent to radiation within a prescribed wavelength to thereby pass the radiation into the interior area. The treatment chamber is formed in the interior area for receiving the fluid be treated , and the fluid carries one or more contaminants to which a photo activating agent is bound. The reference teaches that a single source of radiation is positioned outside the housing. The system envelopes both the housing and source with a reflective surface that focuses radiation from the source or sources into the housing (see column 2). The reference figure 1 shows a system 10 for treating fluid carrying a contaminant. The system includes a treatment device 12 that receives fluid from a source container 14 and conveys after the fluid treatment to a collection chamber 16. The fluid in the source container 14 includes a photo active material that has an affinity for biological contaminant carried by the fluid. The treatment device 12 includes a housing 18 (refers to the overlap of the instant claims) that defines a treatment chamber 20. the housing wall 22 is made from a material that is essentially transparent to the radiation to thereby pass the radiation into the accurate gap 26. The radiation

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chamber 50 includes single source of radiation 52 and a reflector that envelops both the radiation source 52 and treatment device 12. The reference in figure 14 shows the treatment chamber, which includes a inlet 30 to the treatment device 12 includes the length of flexible inert plastic tubing 34. The tubing 34 includes a conventional filter 100 for removing the white blood cells from the fluid prior to entering the treatment device.

The reference does not recite different photo activating reagents such as psoralen, methylene blue and phthalocyanine. However, Foley et al teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines and methylene blue.

The claimed invention differs from the combined teachings of references Bischof et al and Foley et al by reciting a kit. However, based on the reference disclosure of apparatus, it would be obvious to one skilled in the art at the time of the invention to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime.

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is

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on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
26 July 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER